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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,197	03/17/2004	Claus D. Buergelt	5853-371	3776

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EXAMINER	
OGUNBIYI, OLUWATOSIN A	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,197	BUERGELT ET AL.	
	Examiner	Art Unit	
	Oluwatosin Ogunbiyi	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2007 and 05 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/5/07 has been entered.

Status of Claims

Claims 1-5 are pending. Claims 6-20 have been cancelled. The indicated allowability of claim1-5 is withdrawn in view of the new rejections stated below.

Rejections Withdrawn

1. The rejection of claims 6-14 under 35 USC 112, 2nd paragraph as being incomplete for omitting essential steps of detecting a PCR product of a particular size is withdrawn in view of Applicant's cancellation of the claim.
2. The rejection of claims 6,7,8,9 and 11 under 35 USC 102(b) as being clearly anticipated by Englund et al is withdrawn in view of Applicant's cancellation of the claim.
3. The rejection of claims 6,7,8,9 and 11 under 35 USC 102(b) as being clearly anticipated by Erume et al is withdrawn in view of Applicant's cancellation of the claim.
4. The rejection of claims 6,7,8,9,11,12 and 13 under 35 USC 102(a) as being clearly anticipated by Herrewegh et al is withdrawn in view of Applicant's cancellation of the claim.

5. The rejection of claims 6,7,8,9,10,11 and 13 under 35 USC 102(a) as being clearly anticipated by Corti et al is withdrawn in view of Applicant's cancellation of the claim.
6. The rejection of claims 7,9 and 14 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicant's cancellation of the claim.
7. The rejection of claims 7,9 and 14 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of Applicant's cancellation of the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The indicated allowability of claim1-5 in the previous final office action mailed is 7/6/2007 is withdrawn in view of the new rejections stated below.

1. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Englund et al. Diagn. Microbiol Infect Dis vol. 33 p. 163-171, 1999 in view of Vary et al. Journal of Clinical Microbiology, May 1990, p.933-937, Green et al. Nucleic acids Research vol. 17:9063-9073, 1989 and Mahbubani et al in PCR Technology Current Innovations 1994, CRC Press Inc., Chapter 31.

The claims are drawn to A method for detecting a Mycobacterium avium subsp.paratuberculosis (Map) infection in an animal, the method comprising the steps of:

(A) providing a biological sample from the animal and extracting nucleic acids from the sample; and

(B) subjecting the extracted nucleic acids to polymerase chain reaction (PCR) using primers SEQ ID NO: 1 and SEQ ID NO: 2, wherein the presence of an amplification product specific for Mycobacterium avium subsp, paratuberculosis in the polymerase chain reaction mixture indicates that the animal is infected with Mycobacterium avium subsp, paratuberculosis wherein

the animal is a cow

The specification on page 7 lines 19-26 disclose that SEQ ID NO: 1 and SEQ ID NO: 2 are primers specific for the IS900 region of the Map genome.

Englund et al teach a method for the detection of *Mycobacterium avium ssp paratuberculosis* in bacterial cultures from bovine tissue and fecal samples (abstract, materials and methods page 164 under mycobacterial strains and growth conditions) comprising subjecting bacterial colonies obtained from bovine tissue and fecal samples to PCR primers for amplifying the IS900 region of the *Mycobacterium avium ssp paratuberculosis* genome.

Englund et al does not teach a method for detecting MAP infection using primers SEQ ID NO: 1 and SEQ ID NO: 2.

Vary et al teaches that IS900 (of Map genome) represents a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection (p. 935 under discussion).

Green et al teach the sequence of the IS900 region of Map.

Mahbubani et al teaches that PCR amplification and the selection of targets and their primers are routine for the detection of various microbial pathogens (first sentence of discussion on p. 323).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to design any pair of primers to detect the IS900 region of MAP because Englund et al teach that PCR amplification of the IS900 region of Map is used to detect MAP infection and Englund et al teaches PCR primers to the IS900 region that detect Map infection and because Mahbubani teaches that PCR amplification and the selection of primers (and targets) are routine for the detection of various microbial pathogens. Englund teaches that amplification based on IS900 has been developed and widely used for the identification of Map (P. 164 first full paragraph). Vary et al also teaches that IS900 (of Map genome) represents a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection. Thus, one

of ordinary skill in the art having the IS900 sequence as disclosed by Green et al and the teaching that PCR amplification of the IS900 region is sufficient for Map detection can design any set of primers anywhere along the length of the IS900 sequence to arrive at the instant invention (i.e. detection of Map infection) with a reasonable expectation of success.

2. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erume et al. African Health Science vol.1 pg. 83-89, 2001 in view of Vary et al. Journal of Clinical Microbiology, May 1990, p.933-937, Green et al. Nucleic acids Research vol. 17:9063-9073, 1989 and Mahbubani et al in PCR Technology Current Innovations 1994, CRC Press Inc., Chapter 31.

The claims are drawn to A method for detecting a Mycobacterium avium subsp.paratuberculosis (Map) infection in an animal, the method comprising the steps of:
(A) providing a biological sample from the animal and extracting nucleic acids from the sample; and
(B) subjecting the extracted nucleic acids to polymerase chain reaction (PCR) using primers SEQ ID NO: 1 and SEQ ID NO: 2, wherein the presence of an amplification product specific for Mycobacterium avium subsp, paratuberculosis in the polymerase chain reaction mixture indicates that the animal is infected with Mycobacterium avium subsp, paratuberculosis wherein
the animal is a cow

The specification on page 7 lines 19-26 disclose that SEQ ID NO: 1 and SEQ ID NO: 2 are primers specific for the IS900 region of the Map genome.

Erume et al teach a method of detecting Mycobacterium avium ssp paratuberculosis infection in cattle comprising the steps of providing a biological sample from cattle (pg. 84 see samples under methods), subjecting the biological sample to PCR using a set of primers based on IS900 of Mycobacterium avium ssp

paratuberculosis (see pg. 85 under analysis of clinical samples with nested PCR and table 1).

Erume does not teach a method for detecting MAP infection using primers SEQ ID NO: 1 and SEQ ID NO: 2.

Vary et al teaches that IS900 (of Map genome) represents a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection (p. 935 under discussion).

Green et al teach the sequence of the IS900 region of Map.

Mahbubani et al teaches that PCR amplification and the selection of targets and their primers are routine for the detection of various microbial pathogens (first sentence of discussion on p. 323).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to design any pair of primers to detect the IS900 region of MAP because Erume et al teach that PCR amplification of the IS900 region of Map is used to detect MAP infection and Erume teaches PCR primers to the IS900 region that detect Map infection and because Mahbubani teaches that PCR amplification and the selection of primers (and targets) are routine for the detection of various microbial pathogens. Also, Vary et al teaches that IS900 (of Map genome) represents a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection. Thus, one of ordinary skill in the art having the IS900 sequence as disclosed by Green et al and the teaching that PCR amplification of the IS900 region is sufficient for Map detection can design primers anywhere along the length of the IS900 sequence to arrive at the instant invention (i.e. detection of Map infection) with a reasonable expectation of success.

3. Claims 1,3, 4,5, are rejected under 35 U.S.C. 103(a) as being unpatentable over Herrewegh et al. EP 1223225A1 published July 17, 2002 in view of Vary et al. Journal of Clinical Microbiology, May 1990, p.933-937, Green et al. Nucleic acids Research vol. 17:9063-9073, 1989 and Mahbubani et al in PCR Technology Current Innovations 1994, CRC Press Inc., Chapter 31.

The claims are drawn to A method for detecting a Mycobacterium avium subsp.paratuberculosis (Map) infection in an animal, the method comprising the steps of:
(A) providing a biological sample from the animal and extracting nucleic acids from the sample; and
(B) subjecting the extracted nucleic acids to polymerase chain reaction (PCR) using primers SEQ ID NO: 1 and SEQ ID NO: 2, wherein the presence of an amplification product specific for Mycobacterium avium subsp, paratuberculosis in the polymerase chain reaction mixture indicates that the animal is infected with Mycobacterium avium subsp, paratuberculosis wherein the animal is a cow, wherein the biological sample is blood, wherein the biological sample is milk.

Herrewegh et al teach a method for detection of Mycobacterium avium ssp paratuberculosis (Mycobacterium paratuberculosis) by providing a biological sample such as blood, feces, Urine, saliva, tissue or milk from an animal (page 4 paragraph 16) and subjecting the biological sample to PCR using a first set of primers (IS900-01 and IS900-04) for amplifying the IS900 region of Mycobacterium avium ssp paratuberculosis genome (page 6 paragraph 25-27). Herrewegh et al teach the method of detection of Mycobacterium avium ssp paratuberculosis as described above in cows.

Herrewegh does not teach a method for detecting MAP infection using primers SEQ ID NO: 1 and SEQ ID NO: 2.

Vary et al teaches that IS900 (of Map genome) represents a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection (p. 935 under discussion).

Green et al teach the sequence of the IS900 region of Map.

Mahbubani et al teaches that PCR amplification and the selection of targets and their primers are routine for the detection of various microbial pathogens (first sentence of discussion on p. 323).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to design any pair of primers to detect the IS900 region of MAP because Herrewegh et al teach that PCR amplification of the IS900 region of Map is used to detect MAP infection and Herrewegh teaches PCR primers to the IS900 region that detect Map infection and because Mahbubani teaches that PCR amplification and the selection of primers (and targets) are routine for the detection of various microbial pathogens. Also, Vary et al teaches that IS900 (of Map genome) represents a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection. Thus, one of ordinary skill in the art having the IS900 sequence as disclosed by Green et al and the teaching that PCR amplification of the IS900 region is sufficient for Map detection can design primers anywhere along the length of the IS900 sequence to arrive at the instant invention (i.e. detection of Map infection) with a reasonable expectation of success.

4. Claims 1,2,3, 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corti et al. BMC Microbiology 2002, 2:15 in view of Vary et al. Journal of Clinical Microbiology, May 1990, p.933-937,Green et al. Nucleic acids Research vol. 17:9063-9073, 1989 and Mahbubani et al in PCR Technology Current Innovations 1994, CRC Press Inc., Chapter 31.

The claims are drawn to A method for detecting a *Mycobacterium avium subsp.paratuberculosis* (Map) infection in an animal, the method comprising the steps of:

(A) providing a biological sample from the animal and extracting nucleic acids from the

sample; and
(B) subjecting the extracted nucleic acids to polymerase chain reaction (PCR) using primers SEQ ID NO: 1 and SEQ ID NO: 2, wherein the presence of an amplification product specific for *Mycobacterium avium subsp, paratuberculosis* in the polymerase chain reaction mixture indicates that the animal is infected with *Mycobacterium avium subsp, paratuberculosis* wherein the infection is a subclinical infection wherein the animal is a cow, wherein the biological sample is milk.

Corti et al teaches a method for detecting *Mycobacterium avium ssp paratuberculosis* (MAP) infection in diary herds (conclusion of abstract section) comprising the steps of providing biological sample (milk) obtained from dairy herds and subjecting the biological sample to PCR using primers for amplifying the IS900 Map specific insertion. Cortis et al teach that the prevalence of 19.7% IS900 PCR positive milk sample showed a wide distribution of subclinical MAP infections in dairy stock, thus detecting subclinical infections (materials and methods pg 4-6 and discussion).

Corti et al does not teach a method for detecting MAP infection using primers SEQ ID NO: 1 and SEQ ID NO: 2.

Vary et al teaches that IS900 (of Map genome) represents a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection (p. 935 under discussion).

Green et al teach the sequence of the IS900 region of Map.

Mahbubani et al teaches that PCR amplification and the selection of targets and their primers are routine for the detection of various microbial pathogens (first sentence of discussion on p. 323).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to design any pair of primers to detect the IS900 region of MAP because Corti et al teach that PCR amplification of the IS900 region of Map is used to detect MAP infection and Corti teaches PCR primers to the IS900 region that detect

Map infection and because Mahbubani teaches that PCR amplification and the selection of primers (and targets) are routine for the detection of various microbial pathogens. Also, Vary et al teaches that IS900 (of Map genome) represents a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection. Thus, one of ordinary skill in the art having the IS900 sequence as disclosed by Green et al and the teaching that PCR amplification of the IS900 region is sufficient for Map detection can design primers anywhere along the length of the IS900 sequence to arrive at the instant invention (i.e. detection of Map infection) with a reasonable expectation of success.

5. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vary et al. Journal of Clinical Microbiology, May 1990, p.933-937 in view of Green et al. Nucleic acids Research vol. 17:9063-9073, 1989 and Mahbubani et al in PCR Technology Current Innovations 1994, CRC Press Inc., Chapter 31.

The claims are drawn to A method for detecting a Mycobacterium avium subsp.paratuberculosis (Map) infection in an animal, the method comprising the steps of:
(A) providing a biological sample from the animal and extracting nucleic acids from the sample; and
(B) subjecting the extracted nucleic acids to polymerase chain reaction (PCR) using primers SEQ ID NO: 1 and SEQ ID NO: 2, wherein the presence of an amplification product specific for Mycobacterium avium subsp, paratuberculosis in the polymerase chain reaction mixture indicates that the animal is infected with Mycobacterium avium subsp, paratuberculosis wherein the animal is a cow.

Vary et al teaches a method for detecting Mycobacterium avium ssp paratuberculosis (MAP) infection in fecal samples from cattle and subjecting said fecal biological sample to PCR using primers for amplifying the IS900 Map specific insertion sequence to detect an amplification product indicating the cattle is infected with Map

(materials and methods, fig. 3, p. 935 left column first full paragraph, discussion first paragraph). Vary et al teaches that IS900 (of Map genome) represents a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection.

Vary et al does not teach a method for detecting MAP infection using primers SEQ ID NO: 1 and SEQ ID NO: 2.

Green et al teach the sequence of the IS900 region of Map.

Mahbubani et al teaches that PCR amplification and the selection of targets and their primers are routine for the detection of various microbial pathogens (first sentence of discussion on p. 323).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to design any pair of primers to detect the IS900 region of MAP because Vary et al teach that PCR amplification of the IS900 region of Map is used to detect MAP infection; and teaches that IS900 (of Map genome) represents a source of highly specific DNA sequences that may be used as DNA probes for detection of Map infection and teaches PCR primers to the IS900 region that detect Map infection. In addition, Mahbubani teaches that PCR amplification and the selection of primers (and targets) are routine for the detection of various microbial pathogens. Thus, one of ordinary skill in the art having the IS900 sequence as disclosed by Green et al and the teaching that PCR amplification of the IS900 region is sufficient for Map detection can design primers anywhere along the length of the IS900 sequence to arrive at the instant invention (i.e. detection of Map infection) with a reasonable expectation of success.

Status of claims

Claims 1-5 are rejected. No claims allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Oluwatosin Ogunbiyi
Patent Examiner
Art unit, 1645

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PRIMARY EXAMINER